

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Eric R. First

Examiner: Lakia J. Tongue

Serial Number: 10/731,973

Art Unit: 1645

Filed: December 9, 2003

Confirmation No. 6433

For: Botulinum Toxin Therapy for Skin
Disorders

Irvine, California

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

**This response to the July 3, 2006 office action amends
claims 1, 6 and 12 and adds new claims 13-16.**

I. The Office Action

The July 3, 2006 non-Final Office Action (the "Office Action") in this application:

1. rejected claims 1-6 and 8-10 under 35 U.S. C. 102 (e);
2. rejected claims 1, 5 and 12 under 35 U.S. C. 102 (e); and
3. rejected claim 12 under 102 (b).

Applicant responds as follows.

II. Claim Amendments

The amendments to claims 1, 6 and 12 are supported by the original specification as explained below:

The amendment adding the limitation “a swelling or scarring of a small nerve that connects two toes” to claims 1 and 6 is supported by at least lines 31-32 on page 2 of the original specification.

The amendment adding the limitation “reconstituted liquid solution” to claims 1, 6 and 12 is supported by at least lines 23-30 on page 11 of the specification.

The term “keloid” is deleted from claim 12.

III. Rejection of claims 1-6 and 8-10 under 35 U.S.C. 102(e)

The Office Action rejected claims 1-6 and 8-10 under 35 U.S.C. 102(e) as being anticipated by Brin et al. (U.S. 2005/0260231) in light of Wikipedia (Online Encyclopedia).

It appears that Wikipedia is no longer used by the United States Patent and Trademark Office as a source of definitions (see attached page dated August 25, 2006 from the Wall Street Journal Law Blog, Exhibit I). Therefore it is not proper to use Wikipedia to support a rejection of any claims.

Additionally, the Office Action states that in light of the Wikipedia definition of the term "neuroma" as "any tumor of cells of the nervous system which are categorized by neurinoma, neurofibroma and neuroblastoma", that the neuroblastoma disclosed in Brin is the neuromas recited in claims 1 and 6. Note that this is not correct because applicant defined neuroma at page 2, lines 31-32 of the specification to mean only "a swelling or scarring of a nerve that connects two toes". Thus, the neuroblastoma of Brin cannot be a neuroma as defined in the present application. To clarify, applicant has amended claims 1 and 6 to delete the word "neuromas" and replace it by the phrase "...a swelling or scarring of a nerve that connects two toes".

For these reasons the rejection should be withdrawn.

IV. Rejection of claims 1, 5 and 12 under 35 U.S.C. 102(e)

The Office Action rejected claims 1, 5 and 12 under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893).

The Office Action states that Kwon discloses a method for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and keratoses with a botulinum toxin.

Notably, Kwon discloses use of a solid drug solution perforator (SSP), which is a device that utilizes *solid* perforators that are themselves made of a mixture of the solid drug with other components to form to form a matrix of solid material. This solid drug material is then formed into blades or needles which are used to penetrate the patient's body, the perforator then dissolving or biodegrading, thereby releasing the drug (see the Abstract and paragraph [0020] of Kwon).

Significantly, Kwon does not disclose or suggest the use of reconstituted liquid solution of botulinum toxin to treat a skin disorder.

The rejected claims have been amended to limit the claims to administration of a reconstituted liquid solution of botulinum toxin. Since, Kwon does not teach or suggest use of any liquid drug and the devices disclosed by

Kwon are all limited to devices which use a solid drug, therefore the claims as amended are patentable over Kwon.

For these reasons the rejection should be withdrawn.

V. Rejection of claim 12 under 35 U.S.C. 102(b)

The Office Action rejected claim 12 under 35 U.S.C. 102(b) as being anticipated by Gassner et al. (U.S. patent 6,447,787) on the basis of the use of the term “keloid” in the claim.

Although applicant does not agree with the Office Action's characterization of the disclosure of Gassner, the word “keloid” has been deleted from claim 12, thereby rendering the rejection moot.

Therefore the rejection should be withdrawn.

VI. New Claims 13-16

New claims 13-16 are limited to administering a reconstituted liquid solution of botulinum toxin using a syringe. Notably, Kwon teaches away from the use of a hollow needle (i.e. a syringe). See e.g. paragraph [0011] of Kwon. A reference which teaches away from a claimed invention cannot be used to reject a claim. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) ("...the district court erred in...disregarding disclosures in the references that diverge from and teach away from the invention at hand." 220 USPQ at 311) (attached as Exhibit II).

Additionally, claims 13-16 are limited to the use of a liquid botulinum solution, and as explained above, Kwon discloses use of only a solid form of a drug.

Thus, claims 13-16 are in condition for allowance because claims 13-16 are limited to (a) administering a reconstituted liquid solution of botulinum toxin using (b) a syringe. Claims 13-16 also contain the limitations set forth above to distinguish the claims over the Brin and Gassner references.

VII. Conclusion

All issues raised in the Office Action have been addressed. Examination and allowance of claims 1-6, 8-10 and 12-16 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

Date: September ____, 2006

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Attached: Exhibit I Webpage of Wall Street Journal Law Blog
 Exhibit II "*W.L. Gore & Associates, Inc. v. Garlock, Inc.*"

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